CONSOL. AMENDED COMPLAINT No. 2:16-cv-1069-RSM

In re JUNO THERAPEUTICS INC.

The Hon. Ricardo S. Martinez, Chief Judge

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WASHINGTON AT SEATTLE

No. 2:16-cv-1069-RSM

CONSOLIDATED AMENDED
COMPLAINT — CLASS ACTION —
FOR VIOLATION OF FEDERAL
SECURITIES LAWS

JURY TRIAL DEMANDED

Lead Plaintiff Gilbert Hoang Nguyen ("Lead Plaintiff") and named plaintiff Jiayi Wan (collectively "Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their Consolidated Amended Complaint against Juno Therapeutics, Inc. ("Juno" or the "Company"), Hans E. Bishop ("Bishop"), Steven D. Harr ("Harr") and Mark J. Gilbert ("Gilbert") (Bishop, Harr and Gilbert are referred to as the "Individual Defendants") (Juno and the Individual Defendants collectively are referred to as the "Defendants"), allege the following based upon personal knowledge as to Plaintiffs and their own acts, and upon information and belief as to all other matters, based upon, *inter alia*, the independent investigation conducted by and through their attorneys, which included, among other things, a review of the Defendants' public documents, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by, and regarding, Juno, conference calls and announcements made by Defendants, economic analysis of Juno's stock price movement and

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pricing volume data, analysts' reports and advisories about the Company, and information readily obtainable on the internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

- 1. This is a class action on behalf of persons or entities who purchased or otherwise acquired Juno common stock between June 4, 2016 and November 22, 2016, both dates inclusive (the "Class Period"), seeking to pursue remedies under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act").
- 2. Juno is a development stage biopharmaceutical company traded on the NASDAQ exchange under the symbol "Juno." The securities fraud committed by Defendants relates to an immunotherapy under development by Juno known as JCAR015, which focuses on the use of chimeric antigen receptor cells ("Car-T") to treat a type of blood cancer called Acute Lymphoblastic Leukemia ("ALL").
- 3. Throughout the Class Period, Defendants repeatedly touted partial positive results regarding JCAR015 from an incomplete preliminary Phase I trial ("hereafter Phase I") that had limited value, and recklessly failed to tell investors that patients were dying from the toxic side effects associated with JCAR015 in the Company's Phase II/ROCKET trial (hereafter "Phase II/ROCKET") that the Company initiated in the third quarter of 2015.
- 4. Juno needed the clinical trials to be successful because two other Companies, Novartis AG ("Novartis") and Kite Pharmaceuticals ("Kite"), Juno's primary competitors in the development of Car-T therapies, were fiercely competing to be the first to market an FDA approved Car-T therapy. To thwart competition from Novartis and Kite, Juno adopted a "fast to market strategy" for JCAR015 with an initial target date to launch the therapy in 2017. To achieve this goal, Defendants repeatedly withheld material information from investors and recklessly misrepresented vital information about the safety and efficacy of JCAR015, including the fact that JCAR015 led to severe neurotoxicity that resulted in death.

- 5. In December 2015, Juno decided to introduce a combination of two chemotherapies, cyclophosphamide ("cy") and fludarabine ("flu") to eradicate a patient's existing T-cells, before the injection of JCAR015 into the patients enrolled in the Phase II/ROCKET trial. Juno claimed that the flu/cy combination would increase the efficacy of the Phase II/ROCKET trial.
- 6. On July 7, 2016, the Defendants were forced to disclose that the FDA had instructed the Company to halt the trial after one young patient had died in May 2016 and two more patients died thereafter, after receiving JCAR015. On this news, Juno's stock price plunged by more than 30%. Juno was left to delay the launch date of JCAR015 to 2018, thereby shattering its ability to be the first to market a Car-T therapy for ALL.
- 7. Defendants, however, continued to downplay the deaths, withholding from the market the whole truth associating JCAR015 with neurotoxicity and death. Although by this time, 15% of patients enrolled in the trial had died due to severe neurotoxicity associated with JCAR015 (three patients out of approximately twenty enrolled), Defendants claimed that it was the addition of flu in combination with JCAR015 that resulted in cerebral edemas, which led to the death of two additional patients.
- 8. Defendants knew or recklessly disregarded that neurotoxicity and the resulting deaths were associated with JCAR015 itself rather than the addition of flu. Defendants had already launched their own investigation, and industry experts knew that (a) reliable and valid scientific studies do not show any correlation between flu and cerebral edema, (b) flu/cy combinations are routinely used to treat chronic lymphocytic patients with no adverse incidence of cerebral edema, (c) most Car-T cell therapies from previous years of use did not result in cerebral edema and (d) severe neurotoxicity reported in the Phase II/ROCKET trial that was associated with JCAR015 led to the death of the patients.
- 9. Days later, on July 12, 2016, after telling the FDA that it was the flu combined with JCAR015 that led to the deaths, Defendants convinced the FDA to lift the hold on the trial, and enroll patients in the Phase II/ROCKET trial by utilizing only cy as a preconditioning regimen to

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attack a patient's existing T-cells. Upon the market learning that the hold had been lifted, the price of Juno common stock rose 9.4%, closing at \$30.42 on July 13, 2016 from its previous day closing price of \$27.79.

- 10. With this second chance, Defendants intensified their campaign misrepresentations and reckless misconduct. From July through November 2016, the Defendants repeatedly misled investors to believe that it was the alleged "intensity" of flu, the chemotherapy used to destroy a patient's existing T-cells, combined with JCAR015, or the genetically modified T-cells engineered by Juno, that caused a rapid expansion of the genetically modified T-cells, which resulted in cerebral edemas, leading to the prior deaths of three patients enrolled in the Phase II/ROCKET trial.
- 11. On November 23, 2016, the truth caught up with the Defendants. At 8:00 a.m. Eastern Standard Time ("EST"), before the market opened, Juno disclosed that it was placing the Phase II/ROCKET trial on a voluntary hold because two additional patients died from cerebral edemas, leading to a total of five deaths of patients treated with JCAR015.
- 12. On this news, Juno's stock price collapsed. The stock price declined \$7.32 per share, or approximately 25%, to close at \$22.56 on November 23, 2016. Since the November 23, 2016 disclosure of two additional deaths, Juno's stock price has continued to decline, and as of the filing of this Amended Complaint, Juno common stock trades under \$19 per share.
- 13. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in market value of the Company's securities, upon the disclosures thereof, Plaintiffs and other members of the Class have suffered significant damages.
- 14. The Individual Defendants, on the other hand, realized substantial profits during the Class Period. While issuing false statements and omitting to disclose material information to investors about the deadly side-effects of JCAR015, Bishop and Harr reaped over \$15 million from sales of Juno stock during the Class Period. Most egregiously, Bishop sold nearly \$14 million while issuing false statements, over three times the value of stock he sold in the previous year. Bishop sold \$8.64 million worth of Juno common stock while making material misrepresentations

and omissions from June through the first partial disclosure, and continued to capitalize on the fraud by selling an additional \$5.2 million worth of common stock while Juno's stock price was inflated from July through the final disclosure on November 23, 2016.

JURISDICTION AND VENUE

- 15. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).
- 16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).
- 17. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b) given that a significant portion of the Defendants' actions, and the subsequent damages, took place within this District. Juno is a corporation incorporated in Delaware with its principal place of business in Seattle, Washington, and the Defendants reside in or around Seattle, Washington.
- 18. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of a national securities exchange.

PARTIES

Plaintiffs

- 19. Lead Plaintiff purchased Juno securities at artificially inflated prices during the Class Period, and suffered damages as a result of the disclosure of federal securities laws violations alleged herein.
- 20. Named plaintiff Jiayi Wan purchased securities at artificially inflated prices during the Class Period, and suffered damages as a result of the disclosure of federal securities laws violations alleged herein.

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Defendants

- 21. Defendant Juno is a Delaware corporation with its executive offices located at 307 Westlake Avenue North, Suite 300, Seattle, WA 98109. Juno's shares trade on the NASDAQ national market system under the ticker symbol "JUNO."
- 22. Bishop is Juno's co-founder, and at all relevant times, has been Juno's President and Chief Executive Officer.
- 23. Harr, has been, at all relevant times, Juno's Chief Financial Officer ("CFO") and Head of Corporate Development. Prior to his appointment as Juno's CFO in March 2014, Harr was the Managing Director and Head of Biotechnology Investment Banking at Morgan Stanley.
- 24. Gilbert was appointed as Juno's Chief Medical Officer ("CMO") in March 2014 and continues to hold that position. As CMO, Gilbert is responsible for leading and implementing the clinical direction of the Company, and providing medical oversight and expertise related to Juno's immunotherapies.
- 25. Bishop, Harr and Gilbert are sometimes referred to herein as the "Individual Defendants."

BACKGROUND AND PRE-CLASS PERIOD EVENTS

Chimeric Antigen Receptor Therapy ("CAR-T") and JCAR015

- 26. Defendant Juno is a clinical-stage immunotherapy company that focuses on the use of Car-T therapy to treat blood cancer. Immunotherapy aims to harness the patient's own immune system to marshal a response against cancerous tumors.
- 27. The first step of Car-T therapy involves the withdrawal and collection of white blood cells from a patient. T-cells, which can attack cancerous cells, are then isolated from the white blood cells in a laboratory, and engineered to produce Cars or proteins that destroy tumorous cells. A typical Car-T therapy patient is first given standard chemotherapy to eradicate the patient's existing T-cells in an effort to allow the modified T-cells to grow inside the patient's body. The modified Car-T cells are then injected into the patient to recognize and destroy cancerous cells.

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- 28. Although Juno claims that Car-T therapy is a groundbreaking cure for blood cancer, the therapy has serious and deadly side effects, including severe neurotoxicity in the nervous system that can damage the brain and cause cerebral edemas leading to death.
- 29. This lawsuit arises out of the Defendants' material misrepresentations and reckless failure to disclose material information regarding JCAR015, a Car-T therapy, which Juno refers to as one of its most "advanced product candidates" that is the primary subject of the Company's "fast to market strategy." JCAR015 is designed to target CD19, a protein found on the surface of B cell leukemia and lymphomas. Specifically, JCAR015 is designed to target ALL.
- Juno does not currently market any FDA approved drugs to the public. Novartis 30. and Kite are Juno's main competitors that are also developing immunotherapies that target ALL. In an effort to thwart competition from Novartis and Kite, Juno raced ahead with its "fast to market strategy" for JCAR015 with an initial target date to launch the product in 2017.

The FDA Drug Approval Process

- 31. A biopharmaceutical company generally conducts clinical trials in three phases. These phases are codified in FDA regulations.
- 32. Phase I studies "are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." 21 C.F.R. § 312.21.
- 33. Phase II studies are "typically well controlled" studies "conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug." Id.
- 34. Phase III studies are expanded studies "performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects." Id.

- 35. Juno has initiated a Phase I clinical trial to treat ALL entitled "Precursor B Cell Acute Lymphoblastic Leukemia (B-ALL) Treated with Autologous T Cells Genetically Targeted to the B Cell Specific Antigen CD19." Although the Company repeatedly touted partial results from the Phase I study, this trial is not expected to be complete until January 2017. In the third quarter of 2015, Juno initiated a Phase II trial for JCAR015, which the Company refers to as the "ROCKET" trial. Juno aggressively attempted to complete the Phase II trial before December 2017, but the Company was forced to admit that serious safety problems associated with the ROCKET trial have made that goal impossible.
- 36. When a sponsor has conducted sufficient well-controlled clinical trials, and those trials demonstrate substantial evidence of efficacy and safety consistent with the Food, Drug and Cosmetic Act of 1938, the sponsor may prepare and file a New Drug Application ("NDA") with the FDA seeking approval to market the subject drug in a specific dose for the treatment of a specific condition or "indication." The NDA must also specify how the drug will be manufactured, packaged and labeled. The FDA can only grant approval when presented with scientific evidence meeting the requisite statutory criteria.
- 37. If the FDA determines that a trial protocol exposes subjects to unreasonable and significant risk, the FDA can halt or limit the trial by placing it on a total or partial "clinical hold." 21 C.F.R. § 312.42(b). FDA Regulations require the agency to inform the sponsor of a deficiency and attempt to resolve the matter before issuing a clinical hold, unless patients are exposed to a serious and immediate risk. 21 C.F.R. §312.42(c).

Bishop's Past Experience

38. Bishop has a checkered past as a former senior officer of Dendreon Corporation ("Dendreon"), which was another immunotherapy company that went bankrupt after its officers, including Defendant Bishop, allegedly orchestrated a fraud on the market regarding the viability of its products. Bishop's past alleged misconduct put him on notice of the consequences of failing to disclose material information to investors.

39. Between January 2010 and September 2011, Bishop served as the Executive Vice President and Chief Operating Officer of Dendreon. Dendreon declared bankruptcy two years ago after disappointing sales of its lead cancer drug, Provenge, which was a forerunner of the Car-T therapy Juno is currently developing. In 2011, Dendreon and its executives, including Bishop, were sued for misleading investors about the viability of Provenge. The investors alleged that Bishop cashed in on Dendreon's inflated stock price by selling nearly 31.3% of his total holdings during the Class Period. The investors also alleged that Bishop was fired from Dendreon in connection with the material misrepresentations made about Provenge. In 2013, Bishop and his co-defendants settled the Dendreon related lawsuits for \$40 million. Over 20% of Juno's current employees were previously employed at Dendreon.

The Rocket Trial

- 40. In the incomplete Phase I trial, Juno primarily utilized cyclophosphamide ("cy"), a medication mainly used in chemotherapy, as a pre-conditioning regimen to eradicate the patient's T-cells before injecting the patient's body with genetically engineered T-cells that purport to attack and destroy the cancerous cells.
- 41. In December 2015, Juno decided to introduce a combination of two chemotherapies, cyclophosphamide ("cy") and fludarabine ("flu") to eradicate a patient's existing T-cells before the injection of JCAR015 into the patients enrolled in the Phase II/ROCKET trial. Juno claimed that the flu/cy combination would increase the efficacy of the Phase II/ROCKET trial.
- 42. In May 2016, after the introduction of the flu/cy pre-conditioning regimen, a patient in the Phase II/ROCKET trial died of a cerebral edema. Although Juno later admitted that this patient died as a result of severe neurotoxicity associated with JCAR015, Defendants failed to inform investors of this material fact until two additional patients died of cerebral edemas in the last week of June 2016.
- 43. On July 7, 2016, on the same day that Juno announced that the FDA initiated a clinical hold and told investors that a combination of flu/cy with JCAR015 contributed to the death

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of three patients in the Phase II/ROCKET trial, Dr. Sally Church, an editor and lead writer for the Biotech Strategy Blog ("BSB"),¹ criticized the Defendants for blaming flu as an amplifier that caused patients to die rather than the severe neurotoxicity associated with their own product and noted the following:

- A quick scientific literature search for flu and cerebral edema associated with either Car-T cell therapy or even stem cell transplantation produced **zero** results.
- Flu is commonly used with cy and rituximab as treatment for chronic lymphocytic patients. Several hematologists reported that they were unaware of any cerebral edemas associated with flu or a flu/cy combination.
- An investigation into multiple Car-T cell therapies from previous years revealed no cerebral edemas in the adverse events section.
- Juno's competitors, including Kite, used a similar procedure that did not lead to deaths caused by cerebral edema.
- 44. In addition, the BSB interviewed Dr. Stephen A. Grupp, a director of the Cancer Immunotherapy program at the Children's Hospital of Philadelphia ("CHP") and a renowned expert on T-cell therapies. Dr. Grupp reported that his immunotherapy program at CHP did not uncover any cases of cerebral edema in pediatric ALL patients who were given flu as a preconditioning regimen.

Insider Sales

45. Between June 4, 2016 and July 7, 2016, Bishop and Harr took advantage of Juno's artificially inflated stock price to collectively reap nearly \$10 million in proceeds:

Dr. Church has over twenty years of experience in the pharmaceutical industry in the United Kingdom and the United States. At Novartis Oncology, she co-led the U.S. launch of Gleevec, a medication used to treat certain types of leukemia, bone marrow disorders, and skin cancer. Prior to that, she was an executive at Sandoz Pharmaceuticals in the U.K. She has a Master's degree in Human and Applied Physiology and a Doctorate in respiratory medicine, asthma and Chronic Obstructive Pulmonary Disease. The BSB is a subscription only web based publication that provides commentary on science, innovation and new products with an emphasis on oncology, hematology and cancer immunotherapy.

Insider	Dates of Sales	Shares Disposed	Proceeds
Bishop	6/09/16-6/30/16	206,000	\$8,643,461
Harr	6/10/16	30,000	\$1,299,600
Total		236,000	\$9,943,061

- 46. These sales were dramatically out of line with Bishop's and Harr's previous dispositions. For example, before the Class Period and throughout the previous year, Harr acquired stock options and sold only \$225,000 in stock. In 2015, Bishop sold less than \$4.2 million in stock or less than half the amount he sold between the misrepresentations and omissions made in June 2016 and the partial disclosure of patient deaths in the Phase II/ROCKET trial in July 2016.
- 47. During the period between the first partial disclosure of deaths associated with JCAR015 in July 2016 and Juno's voluntary hold of the Phase II/ROCKET trial in November 2016 with the disclosure of additional deaths, Bishop took advantage of Juno's artificially inflated price to dispose an additional \$5.28 million in stock:

Insider	Dates of Sales	Shares Disposed	Proceeds
Bishop	8/31/16-9/27/16	170,708	\$5,278,985.08

48. In total, Bishop sold nearly \$14 million dollars in stock at artificially inflated prices during the Class Period—over three times the amount that he sold in the previous year.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

49. Throughout the Class Period, Defendants made false and misleading statements about the safety of patients enrolled in the Phase II/ROCKET trial and omitted material information from investors regarding serious adverse events that undermined the safety of patients

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receiving JCAR015 in the Phase II/ROCKET trial. Specifically, the Defendants omitted the following material information from investors and made false and misleading statements about the following facts:

- Defendants failed to disclose to investors that a patient enrolled in the Phase II/ROCKET trial had died from a cerebral edema, but confidentially reported that material fact to the FDA and its Data Safety Monitoring Board ("DSMB").
- While withholding the information of the patient's death in the Phase II/ROCKET trial, between May and the first week of July 2016, Defendants repeatedly made partial and incomplete materially misleading statements to the market about the safety and efficacy of JCAR015.
- Between July 7, 2016 and November 22, 2016, Defendants repeatedly misled the market into believing that a combination of flu/cy with JCAR015 was the cause of patient deaths, and that only cy as a preconditioning regimen would lead to positive results, but failed to tell investors that (a) reliable and valid scientific studies did not show any correlation between flu and cerebral edema, (b) flu/cy combinations were routinely used to treat chronic lymphocytic patients without any adverse incidence of cerebral edema, (c) most Car-T cell therapies from previous years did not result in cerebral edema, and (d) severe neurotoxicity reported in the Phase II/ROCKET trial was associated with JCAR015 itself.
- 50. On June 4, 2016, the start of the Class Period, and several weeks after the purported first patient's death in the Phase II/ROCKET trial, Defendants released a glowing press release about JCAR015, in which Gilbert boasted that:
 - "[t]he ongoing efficacy and duration of response for a large percentage of patients, specifically those who do not go on to stem cell transplant, continues to be impressive . . . [t]hese findings provide us with further confidence about our development strategy and the ongoing Phase II Rocket pivotal trial."
- 51. The statement identified in paragraph 50 was materially false and misleading when made because Gilbert (a) cherry picked partial data from an incomplete Phase I study to tout

JCAR015's safety and efficacy, and (b) recklessly failed to disclose to investors that a patient had died in the Phase II/ROCKET trial due to severe neurotoxicity associated with JCAR015.

- 52. Juno's Code of Business Conduct and Ethics ("Code")² expressly designates Bishop and Haar as the Company's official spokespersons for public comment, press, marketing, technical issues, and clinical and regulatory developments. The Code imposes an affirmative obligation on these Defendants and any other authorized employees, including Gilbert, to provide complete, accurate, relevant, objective and timely information in connection with the Company's public reports and communications.
- 53. Because the Code contemplates that authorized employees may communicate with the public on behalf of the Company, the duties imposed by the Code also apply to Gilbert because, as CMO, he repeatedly made public comments about the clinical developments associated with JCAR015. Gilbert violated the Code in paragraph 52 above by issuing incomplete and outdated information regarding the deadly side effects of JCAR015, which rendered materially misleading, his statements, as well as other statements made by the Company regarding the safety and efficacy of JCAR015.
- 54. The June 4, 2016 press release also provided misleading results from one of JCAR015's incomplete Phase I trials that involved 51 adult patients with ALL, who were treated with either cy or a combination of flu/cy followed by JCAR015, *i.e.*, an infusion of genetically modified T-cells. In the June 4, 2016 press release, Juno specifically touted the following misleading data from the incomplete Phase I trial as a measure of JCAR015's remarkable success:
 - A complete response rate was observed in 23 out of 30 patients with morphologic disease (77%) and in 18 out of 20 patients with minimal disease (90%).
 - Among the responsive patients, complete molecular remission was observed in 19 out of 21 patients (90%) with morphologic disease and in 14 out of 18 patients with

Juno Therapeutics, Inc, <u>Code of Business Conduct and Ethics</u>, Adopted as of December 18, 2014, and amended on July 15, 2015, http://media.corporate-ir.net/media_files/IROL/25/253828/cg/code.pdf.

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minimal disease.

- Durable responses and survival observed in patients who received JCAR015 were comparable to those patients who had undergone a stem cell transplant.
- Severe cytokine release cyndrome (sCRS)—another serious side effect of Car-T therapy—was observed in 27% of patients and Grade 3 or higher neurotoxicity was observed in 29% of patients. Amongst patients with minimal disease, 5% experienced sCRS and 20% had Grade 3 or higher neurotoxicity.
- 55. The positive June 4, 2016 press release caused Juno's stock-price to sky-rocket to a Class-Period high of \$49.72, jumping 16.5%, from a previous closing of \$42.65.
- 56. The statements identified in paragraph 54 were materially false and/or misleading when made, however, because (a) the partial, positive results from an incomplete Phase I trial grossly exaggerated the safety of JCAR015, especially in light of the fact that a patient's death was caused by a cerebral edema due to neurotoxicity associated with JCAR015, (b) Defendants released specific information about the rate of high neurotoxicity in the Phase I trial, while at the same time failed to disclose that a patient in the Phase II/ROCKET trial died as a result of severe neurotoxicity associated with JCAR015, and (c) Defendants violated the Code by issuing incomplete and outdated information regarding the deadly side effects of JCAR015.
- 57. On the heels of the June 4, 2016 press release, Defendants' reckless misrepresentations and misleading statements intensified. Throughout the first half of June 2016, Defendants touted the partial data from the incomplete Phase I trial in public filings and at public healthcare conferences in an effort to convince investors about the long-term viability of JCAR015, while recklessly and repeatedly failing to reveal that a patient had died in the Phase II/ROCKET trial due to a cerebral edema caused by high neurotoxicity associated with JCAR015.
- 58. On June 7, 2016, Harr attended the Jefferies Health Care Conference where he boasted that:

We have across multiple different studies now, somewhere between 82% and 100% complete remission rates. And, in fact, with our *most advanced product candidates*

and our current way we're treating patients, we've now treated 36 patients over the course of the last year in either adults or kids with ALL. And all 36 patients have not only a complete remission, but all 36 patients have the tougher bar of a complete molecular remission. So, standard of care is kind of a 3% to 5% complete molecular remission rate. We're now at 100%.

. . . JCAR015 is our fast-to-market strategy. So, it's currently in a trial that, if positive, will serve as a registration study. You can see we have a complete remission rate of around 80% and a complete molecular remission rate of 65%.

(Emphasis added.)

- 59. The statements identified in paragraphs 58 were materially false and misleading when made because while Harr advised the market about a near perfect rate of remission in Juno's "most advanced product candidates," an implicit reference to JCAR015, and touted partial data from the Phase I trial, Defendants knowingly or recklessly failed to disclose to the market that a patient had died in the Phase II/ROCKET trial due to a cerebral edema caused by high neurotoxicity associated with JCAR015. Harr also violated the Code by issuing incomplete and outdated information regarding the deadly side effects of JCAR015.
- 60. On June 7, 2016, Juno filed a Form 8-K with the SEC that contained a finalized corporate presentation that represented a 66% complete remission rate for JCAR015 and a severe neurotoxicity rate of under 30%.
- 61. The presentation identified in paragraph 60 was materially false and misleading when made because the presentation touted partial and incomplete data from a Phase I trial, but failed to disclose that (a) reliable and valid scientific studies do not show any correlation between flu and cerebral edema, (b) flu/cy combinations are routinely used to treat chronic lymphocytic patients with no adverse incidence of cerebral edema, (c) most Car-T cell therapies do not result in cerebral edema, and (d) severe neurotoxicity reported in the Phase II/ROCKET trial was associated with JCAR015 itself.
- 62. On June 9, 2016, Bishop attended the Goldman Sachs Global Health Care Conference where he made the following material misrepresentations about JCAR015:

"So, our most advanced program is with the product candidate called JCAR015. It's an adult ALL. It's currently enrolling a multicenter Phase II study which we plan to support approval, accelerated approval."

. . .

"So, we're very encouraged by that response rate in the 70% range. Percentage of patients when you look at all-comers getting to a durable response in the 40% range. JCAR015 by the way is pretty, for today, pretty conventional Car-T cell technology, in that we do know selection of incoming cells from the patient. We take what we start with and make the product."

63. The statements identified in paragraph 62 were materially false and misleading when made because Bishop (a) touted to the market that Juno had planned to support the Phase II Rocket trial with "accelerated approval" and hyped partial data from the Phase I trial, to create the impression that JCAR015 was a successful therapy, while recklessly failing to disclose that a patient enrolled in the Phase II/ROCKET had died from a cerebral edema caused by severe neurotoxicity associated with JCAR015, (b) described JCAR015 as a "conventional" Car-T therapy without telling the market that a young patient under the age of 25, who was administered JCAR015 had died from a cerebral edema caused by severe neurotoxicity associated with JCAR015, and (c) violated the Code by issuing incomplete and outdated information regarding the deadly side effects of JCAR015.

"A Bump in the Road"

- 64. On July 7, 2016, Juno announced in a press release that the FDA had placed a total clinical hold on the Phase II/ROCKET trial after two additional patients in the trial died at the end of June 2016. Juno told investors that, up to this point, it had enrolled over 20 patients in the Phase II/ROCKET trial. 20 patients was well below Juno's stated goal of enrolling over 50 patients, and the number of deaths per 20 patients resulted in a high rate of death from severe neurotoxicity associated with JCAR015.
- 65. Also on July 7, 2016, the Individual Defendants participated in a conference call regarding a clinical update on JCAR015. For the very first time, Bishop casually disclosed that

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another patient in the Phase II/ROCKET trial had died from a cerebral edema in May 2016, but attempted to blunt the impact of this belated disclosure by blaming the death on "confounding factors" without disclosing what those "confounding factors" were.

- 66. In response to a direct question from a Leerink Partners analyst, Gilbert admitted for the very first time that all three patient deaths were the result of neurotoxicity associated with JCAR015. Gilbert also stated that all three patients, who died from a cerebral edema, were under the age of 25.
- 67. While Bishop stated that the patient death in May 2016 was reported to the FDA and Juno's DSMB, he omitted any explanation as to why this death was not disclosed to investors. The Company repeatedly touted partial data from a Phase I study to pump investor demand and hype the alleged rate of success for JCAR015 for more than a month before it partially revealed the truth after the FDA placed a clinical hold on the trial.
- 68. Bishop stated that the addition of flu as a pre-conditioning regimen in the Phase II/ROCKET trial increased the incidence of severe neurotoxicity that ultimately caused the death of two patients from cerebral edema in the last week of June 2016. During the Q&A session, the Defendants materially mispresented the deadly consequences of JCAR015 by stating that a flu/cy combination amplified the expansion of T-cells that lead to the two additional deaths.
- 69. The market negatively reacted to the July 7, 2016 revelations by Defendants. Juno's common stock fell \$13.01 per share, or nearly 32%, to close at \$27.81 on July 8, 2016.
- 70. Investors, however, still were not aware of the full truth about the cause of neurotoxicity in patients receiving JCAR015 therapy. Defendants led the market to believe that flu when combined with JCAR015 was the cause of cerebral edema:
 - [Bishop]: "... we believe the addition of fludarabine when combined with JCAR015 is the most likely and the most appropriate modifiable factor. Indeed, with cy alone, which we have used in the greatest number of patients treated in the ROCKET trial to date, there have not been any treatment-related deaths and the incidence of severe neurotoxicity is within the range of what we expected in light of the [Phase I] experience."

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[Gilbert]: "If I was to just expand for a moment, the real key for us in our investigations is that the addition of fludarabine seemed to hasten the expansion so that its early, much earlier, and also much more rapid in its rise."

- 71. The statements identified in paragraph 70 was materially false and misleading when made because the Defendants misled the FDA and the market to believe that a combination of flu/cy with JCAR015 was the cause of death instead of the severe neurotoxicity associated with JCAR015 itself, and failed to disclose that (a) reliable and valid scientific studies do not show any correlation between flu and cerebral edema, (b) flu/cy combinations are routinely used to treat chronic lymphocytic patients with no adverse incidence of cerebral edema, and (c) most Car-T cell therapies do not result in cerebral edema.
- 72. Analysts repeated Defendants' statements that flu, in combination with JCAR015, acted as an amplifier that caused severe neurotoxicity, which resulted in death. For example, a Cowen and Company analyst report published on July 8, 2016 entitled "a bump in the road," echoed Juno's explanation to remove flu and utilize only cy given Defendants' representations based on the Phase I study and the early part of the Phase II/ROCKET trial that a cy only preconditioning regimen had an acceptable tolerability profile.
- 73. On July 12, 2016, Juno announced in a press release that the FDA had removed the clinical hold on the Phase II/ROCKET trial, and that, under a revised protocol, the Company would continue enrollment with only cy as a preconditioning regimen.
- 74. The market reacted positively to Juno's July 12, 2016 press release, causing an immediate jump in stock price by 9.4%, closing at \$30.42 from its previous day closing of \$27.79 on July 12, 2016.

Post-FDA-Hold Material Misrepresentations and Omissions

75. Following the FDA's removal of the clinical hold on July 12, 2016, the Defendants continued to misrepresent the cause of patient deaths in the Phase II/ROCKET trial. Over the next several months, Defendants intensified the material misrepresentations identified in paragraph 70.

76. During a second quarter earnings conference call, on August 4, 2016, Bishop told investors that the alleged "intensity" of flu/cy combined with JCAR015 contributed to some patients experiencing rapid T-cell expansion that resulted in cerebral edemas.

77. The statements identified in paragraph 76 were materially false and misleading when made because Defendants failed to disclose that (a) reliable and valid scientific studies do not show any correlation between flu and cerebral edema, (b) flu/cy combinations are routinely used to treat chronic lymphocytic patients with no adverse incidence of cerebral edema, (c) most Car-T cell therapies do not result in cerebral edema and (d) severe neurotoxicity reported in the Phase II/ROCKET trial was associated with JCAR015 itself.

78. On September 13, 2016, Bishop attended the Morgan Stanley Global Health Care Conference where he repeated the same misrepresentations identified in paragraph 70 and offered the same materially misleading explanation for patient deaths in the Phase II/ROCKET trial:

[Bishop]: "Our most advanced product candidate is JCAR015 which is being studied in adult ALL. It was a trial where we had a setback in the last couple of months with some deaths in the trial. I'm sure we'll cover that. The Phase I portion of that trial gets about 35% to 40% of adults into a long-term remission and that, today, is clearly going to set a new standard of care."

[Bishop]: "... And what we've changed in the protocol was the chemotherapy we use before we give the cells often referred to as the lymphodepletion regime." ... "[i]n our analysis, it was pretty clear that as we increase the intensity of the lymphodepletion, we saw this toxicity emerge. Why? We believe it is multifactorial, but to try to and make this as understandable as possible, as you increase the intensity of lymphodepletion, the cells you gave then grow more quickly. And we believe that the risk of this particular form of neurotoxicity is related to the speed at which the cells grow. So, our recommendation to FDA was to remove fludarabine, in other words, reduce the intensity of lymphodepletion. We've got over 40 patients' worth of experience with Cytoxan alone with JCAR015. And we were encouraged that the benefit to risk of that with Cytoxan alone was acceptable."

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79. The	statements identified in paragraph 78 were materially false and misleading
when made because	e (a) reliable and valid scientific studies do not show any correlation between
flu and cerebral ed	ema, (b) flu/cy combinations are routinely used to treat chronic lymphocytic
patients with no ad	verse incidence of cerebral edema, (c) most Car-T cell therapies do not result
in cerebral edema	and (d) severe neurotoxicity reported in the Phase II/ROCKET trial was
associated with JCA	AR015 itself.

80. On September 29, 2016, Bishop attended the Leerink Partners Rare Disease & Immuno-Oncology Roundtable Conference. At this Conference, Bishop made similar misrepresentations to the ones described in paragraph 78:

[Bishop]: "I think the most important thing, before I come to your question on what happened, Michael, is to remind people that we treated about 50 patients in the Phase I trial with JCAR015 at Memorial. The majority of those, more than 40 patients, were with the Cytoxan-alone pre-conditioning. And it's those data that generated an 80%, some 80%-something response rate with nearly 40% patients getting into the [ph] the CR (15.58). So we think the ROCKET trial, JCAR015, with Cytoxan alone, has got a very good chance of replicating that Memorial Phase I. And if it does, it's on track for setting a new standard of care."

[Bishop] . . . "That clearly didn't play out in the ROCKET study, where we saw associated with the addition of fludarabine unacceptable levels of toxicity, including a number of patient deaths. What happened, we believe, is that, if you increase the degree of lymphodepletion too much, which we clearly did, the cells expand quickly. So, it's not the fludarabine per se that caused the toxicity. It's the increase in intensity in the lymphodepletion, which led to these patients experiencing very, very fast cell expansion."

81. The statements identified in paragraph 80 were materially false and misleading when made because Bishop repeated partial data from an incomplete Phase I trial and a preliminary Phase II study rocked by safety concerns and deadly consequences, while failing to inform investors that (a) reliable and valid scientific studies do not show any correlation between flu and cerebral edema, (b) flu/cy combinations are routinely used to treat chronic lymphocytic patients

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with no adverse incidence of cerebral edema, (c) most Car-T cell therapies do not result in cerebral edema and (d) severe neurotoxicity reported in the Phase II/ROCKET trial was associated with JCAR015 itself.

The Truth Emerges

- 82. On November 23, 2016 at 8.00 a.m. EST Time, Juno announced in a press release that it had voluntarily placed the Phase II/ROCKET trial on hold because two additional patients died of cerebral edemas earlier in the week.
- 83. At 8:30 a.m., Bishop, Gilbert and Harr participated in a conference call to provide investors with details about the recent deaths in the Phase II/ROCKET trial. Bishop stated that "all options remained on the table," including abandoning the trial or starting a new study or moving forward with a trial under a modified protocol. Although Gilbert told investors on the July 7, 2016 conference call that Juno had conducted an "investigation" and definitively determined that the addition of flu rapidly expanded the genetically modified T-cells that resulted in additional patient deaths, he now conceded that the Company needed to conduct a new investigation because two additional patients died despite the removal of flu as a preconditioning regimen to eradicate a patient's existing T-cells.
- 84. On this news, Juno's stock price collapsed. The stock price declined \$7.32 per share, or by nearly 25%, to close at \$22.56 on November 23, 2016. Since the November 23, 2016 disclosure of two additional deaths, Juno's stock price has continued to decline, and currently trades under \$19.00 per share.
- 85. The market understood for the first time the full impact of the safety problems with JCAR015. Later in the day after the conference call, analyst Jason McCarthy of Maxim Group, reduced the target price for Juno's stock from \$50 a share to \$34 a share, primarily due to the removal of JCAR015 as a successful product candidate. McCarthy noted that the Company's excuse for the earlier deaths had to be incorrect because the removal of flu as a preconditioning regimen did not prevent additional patients from dying in the Phase II/ROCKET trial.

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CLASS-ACTION ALLEGATIONS

- 86. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of all persons or entities that purchased or otherwise acquired Juno common stock between June 4, 2016 and November 22, 2016, both dates inclusive, seeking to pursue remedies under §§10(b) and 20(a) of the Exchange Act. Excluded are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.
- 87. Class members are so numerous that joinder of all members is impracticable. Throughout the Class Period, Juno common stock was actively traded on the NASDAQ Global Select Market. Because the overwhelming majority of owners hold shares in street name, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Potential Class members may be identified from records maintained by Juno, their transfer agents, and brokers and banks that hold shares beneficially for investors in street name, and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.
- 88. Plaintiffs' claims are typical of the claims of those of the Class, as all Class members were similarly affected by Defendants' wrongful conduct in violation of federal law complained of herein.
- 89. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class action and securities litigation.
- 90. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:
 - whether the Individual Defendants are control persons of Juno for purposes of the Exchange Act;
 - b. whether Juno and the Individual Defendants failed to disclose material information

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regarding JCAR015 therapy and the Phase II/ROCKET trial;

- c. whether Juno and the Individual Defendants made misrepresentations or omissions with scienter;
- d. whether the federal securities laws were violated by Defendants' acts as alleged herein;
- e. whether the prices of Juno's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- f. whether the Class has sustained damages as a result of the disclosures alleged herein with respect to their Exchange Act claims and, if so, what is the proper measure of damages.
- 91. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.
- 92. With respect to the Exchange Act claims, Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:
 - a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
 - b. the omissions and misrepresentations were material;
 - c. Juno's securities are traded in efficient markets;
 - d. the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
 - e. the Company traded on the NASDAQ, and was covered by multiple analysts;
 - f. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
 - g. Plaintiffs and the Class members purchased and/or otherwise acquired Juno

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- 93. Based upon the foregoing, Plaintiffs and other Class members are entitled to a presumption of reliance upon the integrity of the market.
- 94. Alternatively, Plaintiffs and the Class members are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in violation of a duty to disclose such information, as detailed above.

COUNT I

Violation of § 10(b) of the Exchange Act and Rule 10b-5 (against all Defendants)

- 95. Plaintiffs repeat and reallege the allegations contained in Paragraphs 1 to 94 above as if fully set forth herein.
- 96. This Count is asserted against Juno and each of the Individual Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.
- 97. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon the Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Juno securities;

and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Juno securities and options at artificially inflated prices.

- 98. Specifically, Juno and the Individual Defendants made material misrepresentations and omissions as particularized in Paragraphs 49 to 81.
- 99. By virtue of their positions at Juno, Individual Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Juno and Defendants. In addition to the facts alleged herein demonstrating a strong inference of scienter, certain information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within these Defendants' knowledge and control. As the senior managers of Juno, these Individual Defendants had knowledge of the details of Juno's internal affairs, JCAR015 and the Phase II/ROCKET trial.
- 100. As officers and/or directors of a publicly-held company, and by virtue of their stock sales during the Class Period, Defendants had a duty to disseminate timely, accurate, full and truthful information regarding Juno's business, operations, and financial controls. As a result of the dissemination of the aforementioned false and misleading reports and filings, the market price of Juno securities was artificially inflated throughout the Class Period.
- 101. In ignorance of the adverse facts concerning Juno's operations which were concealed by the misrepresentations and omissions alleged herein, Plaintiffs and the other members of the Class purchased or otherwise acquired Juno securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged upon the disclosure of Defendants' wrongdoing described herein.
- 102. During the Class Period, Juno securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, directly relying on the materially false and

misleading statements described herein, and/or relying upon the integrity of the market, purchased or otherwise acquired shares of Juno securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Juno securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Juno securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

- 103. By reason of the conduct alleged herein, Juno and the Individual Defendants knowingly or recklessly violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.
- 104. As a direct and proximate result of these Defendants' wrongful conduct, Plaintiffs and the other Class members suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period upon the disclosures alleged herein. Juno and Individual Defendants are liable for damages in connection with these losses under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT II

Violation of § 20(a) of the Exchange Act (against all Individual Defendants)

- 105. Plaintiffs repeat and reallege allegations contained in Paragraphs 1 to 104 above, as if fully set forth herein.
- 106. During the Class Period, the Individual Defendants participated in the operation and management of Juno, and conducted and participated, directly and indirectly, in the conduct of Juno's business affairs. Because of their senior positions, they knew the adverse non-public information about Juno's operations, JCAR015 and the Phase II/ROCKET trial.

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CONSOL. AMENDED COMPLAINT

No. 2:16-cv-1069-RSM

107. As officers of a publicly owned company, these Defendants had a duty to disseminate accurate and truthful information with respect to Juno's reports and filings and to correct promptly any public statements issued by Juno which had become materially false or misleading.

- 108. Bishop and Harr were designated as the Company's chief spokespersons on public comment, press, marketing, technical issues, and clinical and regulatory developments. The Code imposes an affirmative obligation on these Defendants and any other authorized employees to provide complete, accurate, relevant, objective and timely information in connection with the Company's public reports and communications. Because the Code contemplates that authorized employees may communicate with the public on behalf of the Company, the duties imposed by the Code also apply to Gilbert because, as CMO, he repeatedly made public comments about the clinical developments associated with JCAR015.
- 109. In addition, the Code imposed on the Individual Defendants a separate obligation to ensure the accuracy of all public filings, including, for example, the presentation regarding JCAR015 that was released in a Form 8-K and filed with the SEC during the Class Period.
- 110. Because of their positions of control and authority as senior officers, these Defendants were able to, and did, control the contents of the reports and public filings that Juno disseminated in the marketplace during the Class Period concerning JCAR015 and the Company's clinical trials. Throughout the Class Period, these Defendants exercised their power and authority to cause Juno to engage in the wrongful acts complained of herein.
- 111. As control persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the primary violations of the Exchange Act committed by Juno as set forth in Count I.

REQUEST FOR RELIEF

Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Lead Plaintiff as the Class

1	Representative;
2	B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by
3	reason of the acts and transactions alleged herein;
4	C. Awarding Plaintiffs and the other members of the Class prejudgment and post-
5	judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
6	D. Awarding such other and further relief as this Court may deem just and proper.
7	DEMAND FOR JURY TRIAL
8	Plaintiffs hereby demand a trial by jury of all issues so triable.
9	
10	Dated: December 12, 2016
11	Respectfully submitted,
12	s/ Cliff Cantor
13	By: Cliff Cantor, WSBA # 17893 LAW OFFICES OF CLIFFORD A. CANTOR, P.C.
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24	POMERANTZ LLP
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(212) 661-1100 Tel: 1 Fax: (212) 661-8665 email: jalieberman@pomlaw.com 2 ahood@pomlaw.com 3 Plaintiffs' Lead Counsel 4 5 Certificate of Service 6 I certify that, on the date stamped above, I caused this document to be filed with the 7 Clerk of the Court using the CM/ECF system, which will send notification of filing by email to counsel of record for all parties. 8 s/ Cliff Cantor, WSBA #17893 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27

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CONSOL. AMENDED COMPLAINT No. 2:16-cv-1069-RSM

Law Offices of CLIFFORD A. CANTOR, P.C.